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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/885,247	07/13/2000	Michael Zasloff	036870-5062-01	5537

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EXAMINER	
CHONG, YONG SOO	
ART UNIT	PAPER NUMBER
1617	

DATE MAILED: 06/26/2006

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No.	Applicant(s)	
	09/885,247	ZASLOFF ET AL.	
	Examiner	Art Unit	
	Yong S. Chong	1617	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *09 January 2006*.

2a)☒ This action is **FINAL**. 2b)☐ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *14-30* is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *14-30* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☐ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☐ Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08) Paper No(s)/Mail Date _____.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____ .
5) ☐ Notice of Informal Patent Application (PTO-152)
6) ☐ Other: _____.

DETAILED ACTION

Status of the Application

A request for continued examination under 37 CFR 1.114, including the fee set forth in 37 CFR 1.17(e), was filed in this application after final rejection. Since this application is eligible for continued examination under 37 CFR 1.114, and the fee set forth in 37 CFR 1.17(e) has been timely paid, the finality of the previous Office action has been withdrawn pursuant to 37 CFR 1.114. Applicant's submission filed on 1/9/2006 has been entered.

Claims 1-13 have been cancelled. Claims 15-16, 18-19 have been amended. Claims 14-30 are pending and are examined herein.

Applicant's presumption that Examiner Jiang intended to use US Patent 5,840,740 instead of US Patent 5,842,740 is confirmed and acknowledged.

All claims are drawn to the same invention claimed in the application prior to the entry of the submission under 37 CFR 1.114 and could have been finally rejected on the grounds and art of record in the next Office action if they had been entered in the application prior to entry under 37 CFR 1.114. Accordingly, **THIS ACTION IS MADE FINAL** even though it is a first action after the filing of a request for continued examination and the submission under 37 CFR 1.114. See MPEP § 706.07(b). Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not

mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the mailing date of this final action.

Claim Rejections - 35 USC § 103

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

> (a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

The factual inquiries set forth in Graham vs John Deere Co., 383 U.S. 1, 148 USPQ 459 (1966), that are applied for establishing a background for determining obviousness under 35 U.S.C. 103(a) are summarized as follows:

1. Determining the scope and contents of the prior art.
2. Ascertaining the differences between the prior art and the claims at issue.
3. Resolving the level of ordinary skill in the pertinent art.
4. Considering objective evidence present in the application indicating obviousness or nonobviousness.

Claims 14-30 are rejected under 35 U.S.C. 103(a) as being unpatentable over Zasloff et al. (5,792,635) or Zasloff et al. (5,840,740) in view of the Merck Manual of Diagnosis and Therapy (17th ED).

Zasloff et al. (5,792,635) discloses that administering the instant compound,

compound 1436 (see its structure at col. 9-10, 115-116, 159) with a pharmaceutically acceptable carrier (see col. 4 line 61-65), is useful in methods of treating cardiac infarction, angina pectoris and ischemic disorders of the heart, and anti-ateriosclerotic. and diabetic composition and diabetes, and hypertension in a mammal (see col. 4 line 5-15; col. 1 line 63-65; col. 2 line 21-22). Zasloff et al. also discloses that the dose to be effective in treating diabetes, or effect on insulin secretion is 20 mg/kg/day or by 10 mg/kg, i.v., twice a day (see col.83, Table 11), which is within the instant claimed range.

Zasloff et al. (5,840,740) discloses that administering the instant compound, compound 412 (see its structure at col. 41-42) and compound 1436 (see col. 9-10) with a pharmaceutically acceptable carrier (see col. 4 line 61-65), is useful in methods of treating cardiac infarction, angina pectoris and ischemic disorders of the heart, and anti-ateriosclerotic, and diabetic composition and diabetes, and hypertension in a mammal (see col . 4 line 5-15; col .1 line 63-65; col.2 line 21-22). Zasloff et al. also discloses that the dose to be effective in treating diabetes, or effect on insulin secretion is 20 mg/kg/day or by 10 mg/kg, i.v., twice a day (see col. 79, Table 11), which is within the instant claimed range.

Zasloff et al. do not expressly disclose the employment of the compound therein in a method of reducing blood cholesterol levels in a mammal or reducing blood cholesterol levels in a mammal suffering hypercholesteremia or a mammal suffering hypercholesteremia associated with diabetes.

Note that Zasloff's method treats atherosclerosis in a mammal since atherosclerosis is a known generic term for diseases including cardiac infarction, angina

pectoris and ischemic disorders of the head, and ateriosclerotic diseases, and diabetic composition and diabetes, hypercholesteremia and hypertension in a mammal (see the the Merck Manual of Diagnosis and Therapy, 17th ED page 1654-1656). The Merck Manual of Diagnosis and Therapy also teaches that elevated serum cholesterol or hypercholesterol, hypertension diabetes mellitus, and obesity are the major risk factors for atherosclerosis (see page 1656 both left and right column entitled by "Risk Factors" and subtitles "Hypertension" "Diabetes mellitus" and "obesity).

It would have been obvious to a person of ordinary skill in the art at the time the invention was made to employ the particular compound of Zasloff et al., in methods of treating serum cholesterol, or elevated serum cholesterol, or reducing blood cholesterol levels in a mammal suffering hypercholesteremia or a mammal suffering hypercholesteremia associated with diabetes.

One having ordinary skill in the ad at the time the invention was made would have been motivated to employ the particular compound of Zasloff et al., in methods of treating hypercholesteremia, or elevated serum cholesterol, or reducing blood cholesterol levels in a mammal suffering hypercholesteremia or a mammal suffering hypercholesteremia associated with diabetes, since the prior art compounds are known to be used in treating cardiac infarction, angina pectoris and ischemic disorders of the head, and ateriosclerotic diseases, and diabetic composition and diabetes, and hypertension in a mammal. Moreover, elevated serum cholesterol or hypercholesteremia, hypertension, diabetes mellitus, and obesity are well known major risk factors for atherosclerosis and associated with atherosclerosis according to The

Merck Manual of Diagnosis and Therapy.

Therefore, one of ordinary skill in the art would have reasonably expected that the prior art compounds, would have beneficial therapeutic effects and usefulness in methods of treating hypercholesteremia, or elevated serum cholesterol, or reducing blood cholesterol levels in a mammal suffering hypercholesteremia or a mammal suffering hypercholesteremia associated with diabetes.

Moreover, the patient population for atherosclerosis or diabetes or cardiac infarction, angina pectoris and ischemic disorders of the heart, is reasonably interpreted to encompass or overlap or coincide those patients suffering elevated serum cholesterol as claimed herein, in particular those hypercholesteremia associated with atherosclerosis or diabetes.

Thus the claimed invention as a whole is clearly prima facie obvious over the combined teachings of the prior art.

Response to Arguments

Applicant argues that since aminosterols were observed to increase glucose levels, it would actually teach against using aminosterols in persons suffering from diabetes, since elevated blood glucose levels are often indicative of diabetes.

Examiner reminds Applicant that the prior art references clearly disclose the treatment of diabetes, among many other diseases, through the inhibition of NHEs by aminosterols. Examiner also reminds Applicant that "reducing blood cholesterol levels" and "reducing blood glucose levels" are considered preamble and will be given little

patentable weight. The claims are drawn to method of treating a mammal suffering from hypercholesteremia or diabetes.

It is respectfully pointed out that a recitation of the intended use of the claimed invention must result in a structural difference between the claimed invention and the prior art in order to patentably distinguish from each other. If the prior art structure is capable of performing the intended use, then it meets the claim. In a claim drawn to a process of making, the intended use must result in a manipulative difference as compared to the prior art. See *In re Casey*, 152 USPQ 235 (CCPA 1967) and *In re Otto*, 136 USPQ 458, 459 (CCPA 1963). Thus, the intended use of a composition claim will be given no patentable weight.

It is further respectfully pointed out that a preamble is generally not accorded any patentable weight where it merely recites the purpose of a process or the intended use of a structure, and where the body of the claim does not depend on the preamble for completeness but, instead, the process steps or structural limitations are able to stand alone. See *In re Hirao*, 535 F.2d 67, 190 USPQ 15 (CCPA 1976) and *Kropa v. Robie*, 187 F.2d 150, 152, 88 USPQ 478, 481 (CCPA 1951). See MPEP 2111.02.

Applicant also argues that "arteriosclerosis" is not the same as "atherosclerosis" because arteriosclerosis is a term encompassing several diseases, while atherosclerosis is a particular form of arteriosclerosis. Furthermore, at least some manifestations of arteriosclerosis are not due to elevated levels of blood cholesterol and treatment of a risk factor is not the same as treating a disease state that may have resulted from the risk factor.

Examiner acknowledges that while all manifestations of arteriosclerosis are not due to elevated levels of blood cholesterol, some undoubtedly are. Since elevated blood cholesterol levels are indicative of a disease state, the same compound would have a reasonable expectancy of successfully treating the associated disease as well as the symptom. Examiner reminds Applicant that the standard for obviousness is not absolute success or correlation, but a reasonable expectancy of success. Therefore, since atherosclerosis is a particular form of arteriosclerosis and that the art teaches that elevated serum cholesterol is a major risk factor for atherosclerosis, one would have had a reasonable expectancy of success for treating arteriosclerosis also.

Conclusion

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Yong S. Chong whose telephone number is (571)-272-8513. The examiner can normally be reached on M-F, 9-6.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, SREENI PADMANABHAN can be reached on (571)-272-0629. The fax phone number for the organization where this application or proceeding is assigned is (571)-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

YSC

SHENGJUN WANG
PRIMARY EXAMINER